

Serial No.: 10/663,006

Docket No.: ECV-5662

Amendment After FINAL dated November 20, 2006

Responsive to the FINAL Office Action dated September 21, 2006

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REMARKS/ARGUMENTS

Prior to the present Office Action, claims 12-22 were pending.

Claims 12-13 and 15-16 stand rejected under 35 USC §102(e) as being anticipated by Schoon, et al. (USPN 2003/0078651). Applicants respectfully disagree with the Examiner's 5 reading of Schoon, et al., who only disclose a sizer/marker, and not a suture template.

Claim 12 includes the ultimate step of attaching the plurality of sutures to the prosthetic valve and fixing the prosthetic valve at a location of the heart that is to receive the prosthetic valve. In this case, *the plurality of sutures* are those that have been placed through the plurality of notches of the suture template and through the location of the heart.

10 Schoon, et al. disclose that sutures can be used as markers. In each of passages in paragraphs 46, 62, 84, 88, and 90, sutures may be used as guide markers only. These are not sutures that are used to implant the prosthetic heart valve (i.e., they are "guide sutures" as opposed to "implant sutures"). The Examiner cites paragraph 98 for the step of "attaching the plurality of sutures to the prosthetic valves." However, Schoon, et al. only describe placing 15 implant sutures at the *previously formed* dye marks. The following is the particular quote:

20 In the preferred embodiment, the sizer/marker posts and scallops are oriented to assure clearance of the coronary ostia. For example, marking at the inflow edge can result in three 120 degree spaced *dye marks* aligned in a plane slightly below the patient's excised aortic leaflets. *Three sutures may then be placed using a vertical interrupted technique such that the distal end of each suture exits from the tissue at each mark.* The distal suture ends are then passed through the inflow edge of the valve prosthesis at their corresponding 120 degree spaced markings. The sequence of suture routing, number of sutures, and method of suture placement may be at the discretion of the surgeon. 25 (Emphasis added)

25 That is, the dye marks are first made, then the three implant sutures are placed at each mark. This description supposes dye marks, which could just as easily be the sutures used to mark in another embodiment. This particular passage describes the implant sutures placed using the marks, whether dye or sutures. There is simply no basis for concluding that the guide sutures 30 are also the implant sutures, which is what is required in claim 12.

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Also, Applicants maintain that the sizer/marker of Schoon, et al. has already been removed prior to valve implant because there is no discussion of maintaining it in position. The Examiner responds that Schoon, et al. does not disclose the step of removing the sizer/marker in paragraph 98. However, the omission of the step of removing the sizer/marker does not mean that it remains in place. Applicants assert that the various means for marking tissue disclosed in Schoon, et al. are all done and then quite plainly the sizer/marker tool is removed prior to valve implant. For example, sizer/marker tools for tattooing or cooling tissue include structure that would not only interfere with visualization of the implant suture, but would interfere with functioning of the implanted prosthetic valve. Furthermore, the embodiments where sutures are used for marking specifically utilize a "separate marker" for delivering the sutures guided by "position indicators" in the sizer/marker template (see, e.g., paragraphs 62 and 82). In this case, the separate marker would by necessity be removed prior to valve implant.

Although there is no explicit mention of first removing the sizer/marker tool (except for the use of a separate marker as noted above), leaving the tool in place would tend to occlude the marks made, and interfere with visualization during implant. This is contrary to the central focus of Schoon, et al. In the portion describing use of the invention, Schoon, et al. in paragraph 96 states that marks are made "to assist with the implantation of the prosthesis." Then in paragraph 97, the "position of the markings specifically guides the placement of sutures or other fasteners, such as staples." If the sizer/marker tool is left in place, Applicants assert that the tool would interfere with the guiding purpose of the marks. Because it is apparently removed, Applicants assert that the "implant sutures" are not passed through the notches in the suture template, as stated in claim 12.

Applicants again respectfully assert that claim 12 describes a method of implanting a prosthetic heart valve using a template that guides the placement of the implantation sutures themselves, and remains in place while the implantation sutures are anchored into tissue. This is not the case with Schoon, et al. which merely mentions sutures in conjunction with the

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sizer/marker as an alternative indicator, much like ink or dye. Accordingly, Applicant believes that claim 12 and its dependents are allowable over Schoon, et al.

Claims 14 and 17 stand rejected under 35 USC §103(a) as being obvious over Schoon, et al. Applicants assert that base claim 12 is allowable over Schoon, et al., and therefore these rejections are rendered moot.

Furthermore, Applicant asserts that the Examiner's combination of Schoon, et al. with the suture organizer disclosed in Donlon, et al. (USPN 6,651,671) lacks motivation. In particular, there is no discussion of placing the implant sutures using the sizer/marker of Schoon, et al., let alone utilizing the sizer/marker in conjunction with a suture organizer. Therefore, claims 18-22 are believed to be even further distinguished.

If there is any further hindrance to allowance, the Examiner is encouraged contact the undersigned by telephone.

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Respectfully submitted,

  
Guy Cumberbatch, Registration No. 36,114  
Telephone: (805) 201-3006  
c/o Rajiv Yadav, Registration No. 43,999  
Edwards Lifesciences LLC  
Law Department  
One Edwards Way  
Irvine, California 92614  
Telephone: (949) 250-6801  
Facsimile: (949) 250-6850  
Customer No. 30452

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